K120954

JUN 5 2013

1.4 510(k) Summary

Submitted by:	Phuong Nguyen Son Regulatory Affairs Manager
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Date Prepared:	4 June, 2013
Classification Name:	Endosseous Dental Implant Abutment (21 CFR 872.3630)
Product Code:	NHA
Trade or Proprietary or Model Name:	NobelProcera PEEK Abutments
Legally Marketed Device(s):	Brånemark System Temporary Solutions (K925766) Neo Implant System (K043195)

Device Description:
NobelProcera PEEK Abutments are endosseous dental implant abutments. They are made from PEEK in natural color or white. The PEEK Abutments are available in a variety of preformed and customized shapes that can be used either as provisional abutments or as healing abutments. The customized PEEK Abutments can be shaped to follow the contour of the tissue intended to surround the definitive abutment. Customized PEEK Abutments must be straight, further design limitations for customized shapes are given in the Instructions for Use.

Indications for Use:
The Nobel Biocare PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

Non-Clinical Testing:
Non-clinical testing was performed to support the decision of safety and effectiveness. Non-clinical testing consisted of Biocompatibility testing following ISO 10993. Cytotoxicity testing using the ISO Elution Method (ISO 10993-5) was performed. Also sterilization validation in accordance with ISO 17665 was performed.

Clinical Testing:
No Clinical test data was used to support the decision of safety and effectiveness.

Conclusions:
The information provided in this submission demonstrates that the device is substantially equivalent to the predicate device.

1.4 510(k) Summary

Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE	PREDICATE
	NobelProcera PEEK Abutments	Brånemark System Temporary Solutions (K925766)	Neo Implant System* (K043195)
Material	Polyetheretherketone (PEEK)	Polyetheretherketone (PEEK)	Polyetheretherketone (PEEK)
Color	Natural & White	Natural	White
Attachment Method	Screw retained Engaging & Non Engaging	Screw retained Engaging & Non Engaging	Screw retained
Intended Use	Healing abutment Provisional abutment	Provisional abutment	Healing abutment Provisional abutment
Duration of Use	180 days	90 days	180 days
Implant/Abutment Connection	Nobel Biocare - External Hex - Internal Conical - Internal Tri-lobe	Nobel Biocare - External Hex - Internal Conical - Internal Tri-lobe	Neoss - Internal Hex
Abutment Profile	- Provisional abutments - Straight walled or designed with Procera system - Healing Abutments - Various anatomical shapes intended for different tooth locations or individually designed with Procera system	Straight walled	- Provisional abutments - Straight walled - Healing Abutments - Various anatomical shapes intended for different tooth locations

*This predicate contains a full implant system including provisional and anatomical healing abutments made of PEEK. This 510(k) is only using these abutments as a predicate device.

K120954

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 5, 2013

Nobel Biocare AB
C/O Ms. Phuong Nguyen Son
Regulatory Affairs Manager
Nobel Biocare USA, Limited Liability Company
22715 Savi Ranch Parkway
YORBA LINDA CA 92887

Re: K120954
Trade/Device Name: NobelProcera PEEK Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 20, 2013
Received: May 21, 2013

Dear Ms. Son:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner

Susan Runner DDS, MA -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use

510(k) Number (if known): K120954

Device Name: **NobelProcera PEEK Abutments**

Indications For Use:

The Nobel Biocare PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.06.05 08:44:23 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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